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TITLE: Breast Cancer Biomarkers Based on Nipple and Fine Needle Aspirates

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FOREWORD

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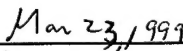
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() In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.



Principal Investigator's Signature



Date

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Grant No: DAMD17-98-1-8083

Project Title: Breast Cancer Biomarkers Based on Nipple and Fine Needle

Aspirates

Principal Investigator: Edward R. Sauter, M.D.

Institutions: Fox Chase Cancer Center, Kansas University Medical Center (KUMC)

Performance Period: 1 May 1998 – 30 April 1999

The purpose of this proposal was twofold: 1) to compare the success of experienced vs. inexperienced individuals in collecting nipple aspirate fluid (NAF) and fine needle aspirate (FNA) samples, and 2) to compare biomarker results in these specimens, including cytology, ploidy, cell cycle parameters, p53, proliferation index, epidermal growth factor receptor, and prostate-specific antigen. Each of these biomarkers has been evaluated in FNA and/or NAF samples. Each of the methods of specimen collection have limitations, suggesting that combining the information gained from each modality may tell the physician more about a subject's breast cancer risk.

At Fox Chase Cancer Center, I have performed breast nipple aspiration on approximately 400 subjects. Samples have been collected on both pre- and postmenopausal subjects, subjects with normal breast cancer risk, with benign breast disease, with atypical hyperplasia, and with invasive breast cancer. KUMC has significant experience performing "blind" fine needle aspiration, i.e., aspiration in an area without a palpable or mammographically visible lesion, having collected specimens from over 300 women. Our goal is to recruit fifty subjects yearly to the proposed trial.

We have thus far received approval from our institutional review board (IRB) at Fox Chase Cancer Center for both the English and the Hispanic versions of the protocol. The protocol is currently under review by the IRB at Kansas University Medical Center (KUMC). In the fall of 1998, I flew to KUMC to learn the FNA procedure as performed at KUMC. I subsequently procured materials (funnels, filters, reagents) required to isolate the cells in a manner similar to KUMC.

Some time after initial approval of the study, I received notice from our institutional review board that the study was on hold. Some members of the committee wanted me to outline in greater detail the nipple aspiration results which I had obtained to date, our success, complications, and so forth. While I expected this to be a quick procedure, it turned out to be a very slow process, lasting approximately 9 months. I am happy to say that the members are now satisfied, and I do not anticipate any further impediments to subject recruitment.